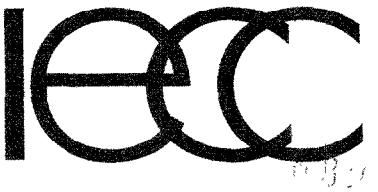

May 15, 2004

RE: Comments of the International Express Carriers Conference on the Joint Food and Drug Administration-CBP and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (Federal Register / Vol. 69, No. 72 / Wednesday, April 14, 2004)

The members of the International Express Carriers Conference (IECC) wish to commend the Food and Drug Administration (FDA) and the Bureau of CBP and Border Protection (CBP) for taking steps to improve integration of their terrorism screening programs. We are particularly pleased with FDA's willingness to consider amending the timeframe for data submissions provided in the prior notice interim final rule (68 FR 58974, October 10, 2003) so that they will match the advanced notice timeframe requirements for arrivals by road, rail or air that are currently required by the CBP's advance electronic information rule. We are convinced that such a change would be fully consistent with the FDA's statutory mandate under section 801(m)(2)(A) of the Food, Drug and Cosmetic Act.

We would like to express our particular support for further refinement to FDA's risk assessment criteria in CBP's Automated Targeting System (ATS). Over time this will almost certainly reduce the number of false positive hits. In addition, the IECC believes that food products subject to the FDA's prior notice requirements should be eligible for streamlined and expedited processing allowed under the CTPAT and FAST programs. By incorporating the information obtained from participants in those programs, the FDA and CBP will be able to reduce the number of flags within their risk analysis systems for those companies.

However, we would also add the caution that coordination of advance notice requirements will be of limited value without improved communications and cooperation between the FDA and CBP to facilitate information exchange and to ensure prompt inspection of shipments subject to prior notice holds. Delays in examining food or food related shipments that are ordered to be held for inspection, the great majority of which will be found not to be in violation of FDA rules, will add substantial costs and inefficiencies to the supply chain. Fast and efficient processing of shipments that are designated for examination will help to minimize additional incurred costs.

<u>Other Issues Related to the Interim Final Rule</u>

We would like to take this opportunity to reiterate comments regarding the Interim Final Rule that we presented to the FDA on January 26, 2004, because we believe that the issues raised are relevant to optimal coordination between the FDA and CBP.

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First, the final interim rule does not make adequate provision for goods that arrive physically at one U.S. port but are entered legally at another, usually inland, port. The interim rule requires that prior notice be provided a certain number of hours before the articles arrive at the first U.S. port of arrival. In many cases, however, international shipments are not legally "entered" with CBP at the port of arrival, but are instead moved under bond to a subsequent port where CBP entry is made. Shipments are not released at that entry port until clearance is obtained from CBP, and carriers are under a strict obligation to retain control of shipments from the arrival port to the legal entry port. However, under FDA's current plan goods will not be permitted to be moved from the port of first arrival to the port of legal entry if for any reason a prior notice that covers them has not been provided. The result could be that express carriers would be required to unload and reload entire planes in order to get at one or two shipments. This is especially problematic because proper facilities for the storage of food may not be available at the ports of arrival. Moreover, the current plan fails to take into account the fact that express consignment operators have invested tens of millions of dollars to construct and operate dedicated sorting facilities that use state of the art automation and scanning equipment. These facilities are far better suited to identifying and detaining food shipments of concern to FDA than the ramps or conventional air freight handling facilities commonly found at the ports of arrival.
Accordingly, we recommend that FDA allow the Bureau of CBP and Border Protection ("BCBP") to screen shipments at the first port of arrival using BCBP's targeting rules. The Prior Notification data can then be submitted at the port where legal entry is accomplished, which have facilities for proper food storage, as well as the BCBP and FDA processes and personnel to deal with any irregularities.

Second, the interim rule does not adequately distinguish between shipments intended for consumption in the United States and shipments that simply transit the United States in a bonded status. While the interim final rules exempt some shipments that transit the United States, for example, food that is imported and exported without leaving the port of first arrival until export), it does not exempt other foreign-to-foreign in-bond transits.

We submit that the prior notice requirement should not be required for shipments that are not intended for U.S. consumption. The current requirement is evidently based on diversion concerns. The risk of diversion from the highly-controlled environment in which express shipments move, particularly in-bond shipments, is negligible, certainly in comparison to the damage that will be caused by detention and spoilage of a large number of foreign-to-foreign shipments that will be affected by this restriction.

Moreover, foreign shippers and foreign consignees do not submit the required Prior Notification data because they are, by design, not be aware that their shipments, on their way to a third country, will transit the United States. Express carriers do not disclose flight routes of packages either to shippers or consignees owing to security concerns. Unless the FDA's rules are changed, express carriers will be required to request these customers to obtain prior notification data, thereby making the customers aware of express carrier routes and nullifying what has heretofore been a simple but effective security precaution.

Third, the FDA's final interim rule does not contain a de minimis exemption for all low value, personal use shipments. While the final interim rule does exempt certain personal use quantities (i.e., food for personal use that accompanies an individual arriving in the United States and food that was made by a private individual in their personal residence and sent by that individual to the United States as a gift), it fails to exempt very similar low-value (e.g., less than $200) commercially-purchased shipments for personal use or gifts. A foreign individual shipping a box of candy as a gift to another individual will not know the Act's requirements. These shipments will likely be detained and left to spoil while express operators attempt to work with a dismayed and confused foreign shipper to obtain the manufacturer's number and registration number. These numbers are not readily available to the consumer when products are purchased in small quantities. We believe that these low value shipments present little risk to the public and should be exempted from the prior notice requirements.

Finally, we wish again to express our gratitude to the FDA for its openness in working with trade operators to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and for its awareness of the need to coordinate its own anti-terrorism programs with those of CBP. We look forward to working with both the FDA and CBP to assure that U.S. trade with other countries is secure and efficient.

Sincerely,

John P. Simpson
Director General

AFTER SEVERAL ATTEMPTS TO TRANSMIT THIS DOCUMENT ELECTRONICALLY, AND AFTER BEING TOLD THAT IT COULD NOT BE SENT BY E-MAIL WE HAVE HAD TO SEND IT BY EXPRESS DELIVERY. WE REGRET THE LATENESS.